K120679

5. 510(k) Summary

JUN - 1 2012

Date Prepared:

February 28, 2012

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902

Telephone: (301) 251-1092
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Contact: Jyh-Shyan Lin

Device Trade Name:

Synapse 3D Nodule Analysis

Device Common Name:

Medical Image Processing and Analysis Software

Regulation Number:

21 CFR 892.2050

Device Classification:

Class II

Device Classification Name:

Picture Archiving and Communications System (PACS)

Panel:

Radiology

Product Code:

LLZ

Date Received:

TBD

Decision Date:

TBD

Decision:

TBD

Predicate Device:

- Advantage Windows Lung Analysis: GE Healthcare (GE Medical Systems) (K042694).

Description of the Device

Synapse 3D Nodule Analysis is an optional software module that works with Synapse 3D Base Tools (V3.0) (K120361, cleared on April 6, 2012). Synapse 3D Nodule Analysis, Synapse 3D Base Tools (V3.0), as well as other optional software modules, all belong to the Synapse 3D product family.

Synapse 3D is the medical application software running on Windows server/client configuration installed on a commercial general-purpose Windows-compatible computer. It offers software tools which can be used by trained medical professionals to interpret medical images obtained from various medical devices, to create reports, or to develop treatment plans.

The key features in Synapse 3D Nodule Analysis include boundary detection of nodules, measurement of nodules, temporal comparison of nodule images, and fusion of CT and PT nodule images on the non-contrast and contrast enhanced CT or PT images.

Synapse 3D Nodule Analysis offers physicians the following clinical applications in addition to the features available from Synapse 3D Base Tools (V3.0) to analyze the image data retrieved from CT and PT devices.

- Response Evaluation Criteria in Solid Tumors (**RECIST**) Tracker
  Use non-contrast and contrast enhanced computed tomography (**CT**) images, provide custom workflows, user interface (UI), and reporting functions for nodule analysis including boundary detection of nodules (based on the location specified by the user), measurement of nodules, temporal comparison of nodule images, and fusion of a CT nodule image on a PT nodule image.
- Positron Emission Response Criteria in Solid Tumors (**PERCIST**) Tracker
  Use positron emission tomography (**PT**) images, provide custom workflows user interface (UI), and reporting functions for nodule analysis including standardized uptake value (SUV) measurement of nodules with sphere VOI (based on the location specified by the user), temporal comparison of nodule images, and fusion of a PT nodule image on a CT nodule image.

Indication for Use

Synapse 3D Nodule Analysis is medical imaging software used with Synapse 3D Base Tools that is intended to provide trained medical professionals with tools to aid them in reading, interpreting, reporting, and treatment planning. Synapse 3D Nodule Analysis accepts DICOM compliant medical images acquired from CT and PT.

This product is not intended for use with or for the primary diagnostic interpretation of Mammography images.

Addition to Synapse 3D Base Tools, Synapse 3D Nodule Analysis is intended to;

- use non-contrast and contrast enhanced computed tomography (CT) images, provide custom workflows and UI, and reporting functions for nodule analysis including boundary detection of nodules based on the location specified by the user, measurement of nodules, temporal comparison of nodule images, and fusion of a CT nodule image on a PT nodule image.
- use positron emission tomography (PT) images, provide custom workflows and UI, and reporting functions for nodule analysis including SUV measurement of nodules with sphere VOI based on the location specified by the user, temporal comparison of nodule images, and fusion of a PT nodule image on a CT nodule image.

Technological Characteristics

Synapse 3D Nodule Analysis introduces no new safety or efficacy issues other than those already indentified with the predicate devices. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."

Testing

Synapse 3D Nodule Analysis is tested successfully with reference to its Software Requirements Specification, as well as design verification and validation documents and Traceability Matrix document. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the Synapse 3D Nodule Analysis software, which is found to be safe and effective and substantially equivalent to the currently-cleared predicate device.

Conclusion

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN - 1 2012

Mr. Jyh-Shyan Lin
Senior Manager, Regulatory, Quality and Clinical Affairs
FUJIFILM Medical Systems, U.S.A., Inc.
419 West Avenue
STAMFORD CT 06902

Re: K120679
Trade/Device Name: Synapse 3D Nodule Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 28, 2012
Received: March 6, 2012

Dear Mr. Lin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Synapse 3D Nodule Analysis

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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